

# Notice of Allowability

Application No.

09/937,837

Examiner

Daniel M Sullivan

Applicant(s)

DALBY ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 19 December 2003.
2. ☒ The allowed claim(s) is/are 12,13,15,16,21-23,25-28,31-36,38-41,51-55,59-61 and 63-70.
3. ☒ The drawings filed on 05 May 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)         |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                 |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance           |
|  | 9 <input type="checkbox"/> Other   |

*Anne Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER

Art Unit: 1636

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sally Sullivan on 26 January 2004.

The application has been amended as follows:

The claims have been amended as follows:

33. The method according to claim 32 wherein the recombinase is a member of ~~the~~ a family of site-specific recombinases selected from the groups consisting of the integrase family of site-specific recombinases and the resolvase/invertase family of site-specific recombinases.

53. The method according to claim 12 wherein the recombinase is a site-specific recombinase and a nucleic acid comprising the target gene further comprises one or more site-specific recombination sites.

Claims 57 and 58 are canceled.

59. ~~The method of claim 58~~ A method for modulating expression of a target gene product in a cell in culture that contains a target gene under control of one or more regulatory elements, said method comprising contacting the cell under suitable conditions with one or more regulatory agents attached to a translocating polypeptide, whereby the one or more regulatory agents are translocated into the cell in culture and interact therein with the one or more regulatory elements, thereby modulating expression of the target gene product by the cell wherein the translocating polypeptide exhibits receptor-independent and energy- free penetration of cell membranes, wherein the cell does not have a cell wall; and wherein the one or more regulatory agents include a DNA-binding protein wherein the DNA-binding domain is that of SEQ ID No: 4.

65. The method according to claim ~~58~~ 59 wherein the translocating polypeptide is a VP22 polypeptide.

68. The method according to claim ~~58~~ 59 wherein the translocating polypeptide and the one or more regulatory agents are units of a fusion protein.

Art Unit: 1636

Claims 69 and 70 have been added:

69. The method according to claim 60 wherein the translocating polypeptide is a VP22 polypeptide.

70. The method according to claim 60 wherein the translocating polypeptide and the one or more regulatory agents are units of a fusion protein.

The following changes to the drawings have been approved by the examiner and agreed upon by applicant: The drawing labeled "FIGURE 6" in substitute drawings filed on 5 May 2003 should be labeled "FIGURE 7" so that the figures match the brief description in the specification. In order to avoid abandonment of the application, applicant must make these above agreed upon drawing changes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS

*Anne-Marie Zalk*  
ANNE-MARIE ZALK, PH.D.  
PRIMA